Impact of Lifestyle on Cardiovascular and Metabolic Risk Factors in Trauma Exposed Post-9/11 Veterans

NCT04911153

February 21, 2024

Participant Name: _____ Date:_____

Title of Study: Impact of Lifestyle on Cardiovascular and Metabolic Risk Factors in Trauma Exposed Post-9/11 Veterans

Principal Investigator: James W. Whitworth, PhD VA Facility: VA Boston Healthcare System_

KEY SUMMARY INFORMATION ABOUT THIS STUDY

We are asking you to be in a research study that will be conducted in person, between you and members of the Translational Research Center for TBI and Stress Disorders (TRACTS) study staff. This study is being supported by the Department of Veteran Affairs Rehabilitation Research and Development Service. Before you decide to take part, you should know why the study is being done and what it will involve. This form tells you what to expect if you agree to be in the study. Taking part in this study is completely voluntary; it is your decision whether or not to participate in the study.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

We are doing this research to compare the accuracy of a physical activity questionnaire to a wearable activity monitor. If you agree, you will be asked to wear a small physical activity monitor on your wrist or hip for a week and participate in two one-hour sessions at VA Boston Healthcare System over the course of two weeks. At the first session you will fill out questionnaires relating to your average physical activity levels, physical and mental health, and receive training on how to wear the activity monitor. The second session will be approximately 9-14 days after the first session, and you will answer the same questionnaires again, and participate in an aerobic exercise test. You will be in the study for two weeks (14 days) if you decide to stay for the whole study. We will describe your involvement in more detail later in this form.

For your safety, the safety of the research staff and members of the VA Boston Healthcare System community all local and VA wide COVID-19 protocol/procedures will be followed throughout the study.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to volunteer in the study because you would like to learn more about wearable activity monitors and/or your own physical activity and fitness levels. You will find more information about benefits later in this form.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may choose not to volunteer to be in the study if you are uncomfortable with exercising, answering questions about your physical activity, or physical and mental health. You will find more information about these risks later in this form.

FOR IRB USE ONLY

VA Boston Healthcare System IRB
Effective Date: February 21, 2024

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. If you are a VA employee or student, your refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. James Whitworth at the VA Boston Healthcare System, Jamaica Plain campus. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: (617) 390-6810 or email james.whitworth@va.gov.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

The goal of this research study is to determine if a simple questionnaire accurately reflects the physical activity measurements from a wearable fitness tracker in post-9/11 Veterans with PTSD. If the simple questionnaire does accurately record physical activity patterns, it will give VA healthcare providers a fast and easy tool to assess physical activity in their patients.

We are inviting you to participate in this VA Rehabilitation Research & Development funded study because you are a current TRACTS participant, and you indicated you may be interested in other related research studies. The total time commitment for the study is two, approximately 1-hour sessions over the course of two weeks. The research is being conducted at the VA Boston Healthcare System, Jamaica Plain. We are aiming to recruit a total of 100 veterans to participate in this study.

HOW LONG WILL I BE IN THE STUDY?

The total time commitment for this study is two study sessions, lasting approximately 1-hour each. Both sessions will occur over the span of two weeks (14 days). Both study sessions will take place at the Jamaica Plain campus of the VA Boston Healthcare System (150 S. Huntington Ave, Jamaica Plan MA, 02130).

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

A detailed description of the study procedures from start to finish are as follows:

Study Session 1 (approximately 1-hour) – After you consent to be in the study, we will review your health history with you to screen for any health conditions where exercise is contraindicated. If no such health conditions are present, you will complete several questionnaires that ask about your current physical activity levels, mental health, and physical functioning. Following the questionnaires, we will teach you how to properly wear a physical activity monitor. Once these procedures are complete, we will schedule you for Study Session 2 (9-14 days after Session 1). You will also be given a physical activity monitor to wear on the days between Sessions 1 and 2.

Wearing the physical activity monitor – You will be asked to wear the activity monitor for at least 7 consecutive days between Study Sessions 1 and 2. The monitor is to be worn during all waking hours (while working, exercising, and leisure activities), with the exception of bathing or swimming. During this time, you will receive daily text/email reminders to wear the monitor.

Study Session 2 (approximately 1-hour) – You will return the activity monitor at the beginning of this session, and then complete the same physical activity questionnaires from Study Session 1. We will then measure your height, weight, and waist circumference. Next, you will be rescreened for any current health concerns that would prevent you from exercising. If none are present and time allows, you will complete a handgrip strength assessment and a cardiopulmonary exercise test to measure your current muscular strength and aerobic fitness (details provided below). After the exercise tests are finished the study is complete.

- Handgrip Strength Assessment – You will be asked to squeeze a small device (handgrip dynamometer) with your dominant hand as hard as you can. The device records the amount of force you can produce with your handgrip. You will get three attempts to do your best. The purpose for this test is to measure your grip strength, which is used as a proxy for overall muscular strength.
- Cardiopulmonary Exercise Test – First, we will measure your resting blood pressure, heart rate and breathing using an electrocardiogram (ECG) and metabolic cart. Next you will warmup by walking on a treadmill. You will continue walking on the treadmill after the warmup. Every three minutes the treadmill speed and/or incline will increase in small increments. During this time, we will be monitoring your heart rate, breathing, blood

pressure, and cheering you on. Your goal is to walk, jog, or run for as long as you can. This is typically around 12-14 minutes; however, the maximum duration of the test is 27 minutes. The purpose of this test is to measure your aerobic fitness (cardiorespiratory fitness).

- Optional Questionnaire / Interview – If you identify as a woman, you will be given the option to complete an optional 10-item questionnaire assessing their interest in engaging in exercise programs made for Women Veterans. Additionally, you will be given the option to participate in an open-ended interview which aims to assess their knowledge of physical activity, and facilitators and barriers to engaging in exercise. We anticipate these questions and interview to take an additional 30-60 minutes.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Comply with all State, local, and VA COVID-19 health and safety guidelines.
- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you might be pregnant.
- Complete your questionnaires and assessments as instructed.
- Wear the activity monitor and return it as instructed.
- Ask questions as you think of them.
- Inform research staff if you are uncomfortable with or wish to discontinue any of the questionnaires/assessments.
- Treat all hospital and study staff with respect. Similarly, you can expect to be treated with respect and dignity. If you feel you were mistreated by any hospital/study staff, please inform the study Principal Investigator (Dr. Whitworth).
- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from completing multiple cardiopulmonary exercises tests without ample rest. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Overall, this study poses low risks to you. You may experience some discomfort in the form of boredom and fatigue when completing assessments and questionnaires. You may also experience emotional distress when completing the questionnaires that ask you to reflect on your mental health and functional/disability status. Every effort will be made by the evaluators to make the process as comfortable as possible. If you become distressed you will be referred to either the Principal Investigator (PI) or a psychologist, to assist with possible treatment or referral. You are free to discontinue your participation at any time.

You may also experience some discomfort while wearing the activity monitor. However, the study staff will train you on how to properly wear the monitor around your waist, to minimize this. The activity monitor does not collect any protected health information or personally identifying information, so there would be no loss of privacy if it were lost or stolen. Additionally, if it is lost or stolen, we will remotely deactivate the device so that it cannot be used.

During the exercise testing you will likely experience sweating, rapid breathing, and discomfort in your muscles from exertion. You may also experience temporary skin irritation from ECG electrode leads, and some delayed onset muscle soreness in the days following the exercise test. These discomforts are expected and normal with exercise testing. There is also a small risk of muscle sprains or pulls, as well as more severe adverse reactions (heart attack or death) with exercise. The risk of a more severe adverse reaction is rare (0.04% or 1 per 2,500 tests). Importantly, all participants are screened for any potential risk factors that may increase the chances of a severe adverse reaction. The PI is a PhD level exercise physiologist with over 10 years of human performance testing and is trained to minimize risk during exercise. Finally, you are free to end the exercise test at any time.

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no anticipated direct benefits to you for being in this study. However, you may learn more about wearable activity monitors and your own health status, physical activity and fitness levels.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Participation in this study is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits. If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress. You may withdraw and still receive the same standard of care that you would otherwise have received. If you decide to withdraw, we do not expect any adverse effects on your health or welfare. For data already collected prior to your withdrawal, the investigator may continue to review the data already collected for the study but cannot collect further information.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law. We will store your information in ways we think are secure.

Your information collected for the purpose of this research study will be kept confidential. Data will be securely stored on a local network behind the VA firewall, in the PI's folder on an encrypted computer. The computer will be secured in a locked office. The results of this study may be published for scientific purposes, but your records or identity will not be revealed. Your signed consent form will also be kept locked in a file separate from your data. Only trained research personnel directly involved in this study will have access to information gathered in this study. Data from this study will be shared with subprojects that are a part of TRACTS. Additionally, other studies under the approval of the VA Boston Healthcare System Institutional Review Board who have received specific approval to use data from TRACTS, via the TRACTS data repository, may also have access, but only if you agree to share your data. All shared data will be de-identified.

Questionnaires and interview data will be completed on a VA computer, or iPad that is non-networked at the time of test administration using Qualtrics. Qualtrics is a platform used to administer surveys/questionnaires by organizations and researchers nationwide, including VA medical centers. Qualtrics has secure transmission services that meet all federal requirements. Your data will be transmitted with your research code, and no personally identifiable data will be

transmitted. Access to your data is limited to authorized study personnel via login to a secure site. A copy of the original data will remain on the Qualtrics server.

Study data collected for the electronic diet assessment (ASA24) will be de-identified, encrypted and stored securely behind the National Cancer Institute's (NCI) firewall. The ASA has secure transmission services that meet all federal requirements. Your data will be transmitted with your research code, and no personally identifiable data will be transmitted. Access to your data is limited to authorized study personnel. A copy of the original data may remain on the NCI server.

If participating in the optional questionnaire and interview for women, this information will be de-identified. A copy of the de-identified survey data will remain on Qualtrics. The interview will be audio-recorded, and a transcript of the recording will be kept behind a VA firewall. Access to this data is limited to authorized study personnel.

To comply with laws and regulations, we may need to share safety-related information such as that relating to child abuse or neglect; elder or disabled person abuse; specific reportable diseases; harm to self or others.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

A participant will not be required to pay for medical care and services received as a participant in an approved VA research study. Some participants are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services (including, but not limited to, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study. **You will be compensated up to $150 for your time and effort taking part in this study.**

- ***You will be compensated $50 for completing Study Session 1***
- ***You will be compensated $50 for completing Study Session 2***
- ***You will be compensated $50 for returning the activity monitor at Study Session 2***

If participating in the optional questionnaire and interview for women-veterans, you will be compensated with a $25 gift card to your choice of Target or Walmart.

You consent to the release of personally identifying information about you including your name, address, and social security number to the VA so that we may provide compensation to you.

If you chose to receive payment via a **check** or **debit card** you consent to the release of personally identifying information about you including your name, address, and social security number to the VA so that we may provide compensation to you. You can expect to receive a check or debit card within 2-6 weeks. The government may garnish the compensation against outstanding debts a veteran has to the federal government.

If you chose to receive payment via **direct deposit** you consent to the release of personally identifying information about you including your name, address, social security number and bank information (bank name, routing number, and account number) to the VA so that we may provide compensation to you. You will receive payment within 7 to 10 days.

If payment is made to you by the VA (whether by check, direct deposit, or a VA issued debit card), an IRS Form 1099 will be generated regardless of the amount you are paid.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?
If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution. You will not be compensated should an injury occur during your participation. By signing this form you do not give up any legal rights or release the VA from any liability by signing the form.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call Dr. James Whitworth at (617) 390-6810.

DO I HAVE TO TAKE PART IN THE STUDY?
Participation in this study is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits. If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress. You may withdraw and still receive the same standard of care that you would otherwise have received. If you decide to withdraw, we do not expect any adverse effects on your health or welfare. For data already collected prior to your withdrawal, the investigator may continue to review the data already collected for the study but cannot collect further information.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

If the study staff determines that you have any health condition that may make participation in this study difficult or unsafe, your participation may be terminated. In the event that this occurs, the PI will meet individually with you to discuss their decision to end your participation and to offer appropriate referrals. The investigator may continue to use the data already collected prior to your termination but cannot collect further information.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any general questions about the study **during the day,** please call **Dr. James Whitworth** at (617) 390-6810.

If you have questions about your rights as a study participant or any other questions, complaints, concerns or suggestions about this study, you may contact the Institutional Review Board at (617) 637-3794. This is the Board that oversees all human research at VA Boston Healthcare Systems and has the responsibility to ensure the safety of human participants in this study.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

Participant Name: _____ Date:_____

Title of Study: Impact of Lifestyle on Cardiovascular and Metabolic Risk Factors in Trauma Exposed Post-9/11 Veterans

Principal Investigator: James W. Whitworth, PhD VA Facility: VA Boston Healthcare System_

FUTURE USE OF DATA AND RE-CONTACT

Your data may be used in the future by other studies under the approval of the VA BHS Institutional Review Board who have received specific approval to use data from TRACTS, via the TRACTS data repository, may also have access, but only if you agree to share your data.

Identifiers might be removed from the identifiable private information and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

_____ **Please initial here if you agree to have your data shared with the TRACTS data repository.**

If you agreed to share your data with the TRACTS data repository (by initialing above), your data will be entered into a data repository and may be used for future studies approved by an Institutional Review Board. Your data will be securely stored on a local VA network behind the VA firewall. Only the research staff of this study and individuals with appropriate approval from the PI and Institutional Review Board will have access to your data.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms._____ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

FOR IRB USE ONLY

VA Boston Healthcare System IRB
Effective Date: February 21, 2024